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APPENDIX V

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The BMI Surgical Staple Marker is substantially equivalent to many staple/marker devices including the BMI Surgical Staple Marker and Ethicon's Titanium Staple, Stapler (Endopath EMS), and LIGACLIP. The BMI device has the same intended use as the marketed predicate devices; these devices' intended use are to be applied to soft tissue during open or percutaneous procedures and radiographically mark the surgical location. The BMI Surgical Staple Marker has technologic characteristics which are substantially equivalent to the BMI and Ethicon predicate devices.

COMPANY AND CONTACT PERSON

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DEVICE NAME

Surgical Staple Marker

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

1. BMI Surgical Staple Marker
2. Ethicon Surgical Staplers (Titanium Staples, Multifeed Stapler, LIGACLIP)

STATEMENT OF INTENDED USE

The Surgical Staple Marker's intended use is to be applied to soft tissue during open or percutaneous procedures and radiographically mark the surgical location.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

1. The BMI Surgical Staple Marker's intended use is to be applied to soft tissue during open or percutaneous procedures; the staple may be used to radiographically mark the surgical location.
2. The Ethicon Staple/Clip's intended use is to be applied to soft tissue during open or percutaneous procedures; the staple may be used to radiographically mark the surgical location.

**STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE
AND PREDICATE DEVICE**

The design, construction, materials, nominal specifications are either identical or substantially equivalent to the marketed predicate devices. The devices consist of a non absorbable material compatible with X-ray, i.e., clearly visible on a radiograph; the staple/markers are deployed with manual appliers or surgical instruments.